RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER
RUSH UNIVERSITY

1725 WEST HARRISON STREET, CHICAGO, ILLINOIS 60612.3824
312.243.4244 FAX: 312.942.1516 E-Mail: bach@ortho4.pro.rpslmc.edu

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DEPARTMENT OF ORTHOPEDIC SURGERY

BERNARD R. BACH, JR., M.D.
PROFESSOR AND DIRECTOR
SECTION OF SPORTS MEDICINE

December 1, 1999

Document Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #97N-484S

Dear Sir/Madam,

My understanding is that there is an FDA proposal to regulate allograft tissue,

As a sports medicine orthopedic surgeon, I utilize non-irradiated allograft tissues currently in approximately 20% of my patients who require knee ligament reconstructive surgery. I have found this tissue to be an important adjunct for treatment in my patient population. As the Director of Sports Medicine at Rush Medical College, I frequently see challenging knee ligament disorders. I utilize allograft tissue in selected situations including revision ligament surgery, multi-ligament injured knees requiring additional tissues for reconstruction, petite women in whom their own tissue is insufficient for ACL reconstruction, simultaneous one stage bilateral knee ligament reconstruction, and in patients who have a combination of ligament insufficiency and degenerative joint disease in whom I am trying to reduce perioperative morbidity.

We had an opportunity last year to clinically review a selected group of our patients who had undergone non-irradiated allograft tissue for revision anterior cruciate ligament knee surgery. The results were very favorable and were comparable to our index ACL reconstruction with autograft tissues.

I am concerned that FDA regulation of allograft tissue may require the sponsorship of clinical trials and submission of lengthy regulatory documents. These and other factors may negatively impact the care of my patients.

In my opinion, a regulation of allograft tissue is unnecessary.

Sincerely,

Bernard R. Bach, Jr., M.D.

BRB/pjv

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RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER
RUSH UNIVERSITY
1653 WEST CONGRESS PARKWAY, CHICAGO, ILLINOIS 60612-3864

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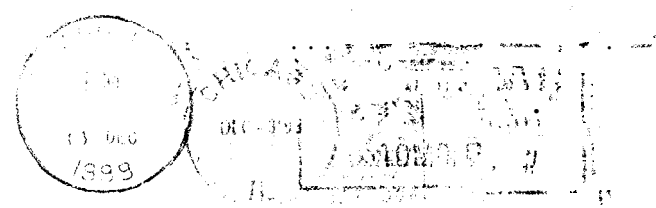

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